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**DEC 15 2009**

**OFFICE OF PETITIONS**

In re Patent No. 7,550,496	:	
Matteucci, et al.	:	DECISION ON
Application No. 10/549,545	:	REQUEST FOR
Issue Date: June 23, 2009	:	RECONSIDERATION OF
Filed: May 26, 2006	:	PATENT TERM ADJUSTMENT
Attorney Docket No.	:	AND NOTICE OF INTENT TO
021305-003900US	:	ISSUE CERTIFICATE OF
	:	CORRECTION

This is in response to the REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d), filed August 21, 2009. Patentees request that the determination of patent term adjustment be corrected from seventy-eight (78) days to four hundred sixteen (416) days.

The request for reconsideration of the patent term adjustment indicated in the patent is GRANTED to the extent indicated herein.

Patentees are given THIRTY (30) DAYS or ONE (1) MONTH, whichever is longer, from the mail date of this decision to respond. No extensions of time will be granted under 37 CFR 1.136.

The patent term adjustment indicated in the patent is to be corrected by issuance of a certificate of correction showing a revised Patent Term Adjustment of one hundred forty-seven (147) days.

**BACKGROUND**

This application was filed on May 26, 2006. On June 23, 2009, the application matured into U.S. Patent No. 7,550,496 with a revised patent term adjustment of 78 days. The Office

determined that the 268 days of Office delay pursuant to 35 U.S.C. 154(b)(1)(B) and 37 CFR 1.702(b)<sup>1,2</sup> overlaps with the 284 days of Office delay pursuant to 35 U.S.C. 154(b)(1)(A) and 37 CFR 1.702(a)(1)<sup>3,4</sup> accorded prior to the issuance of the patent. As such, the Office allowed only entry of the adjustment of 284 days for Office delay. No additional days of patent term adjustment were entered at issuance under the three-year pendency provision. The patent issued with a revised patent term adjustment of 78 days (284 days of Office delay - 206 days of applicant delay.)

On August 21, 2009, patentees timely submitted this request for reconsideration of patent term adjustment asserting that the correct number of days of patent term adjustment is 416 days, based in part, under the courts interpretation of the overlap provision as set forth in Wyeth v. Dudas, 580 F. Supp. 2d 138,

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<sup>1</sup> Pursuant to 35 U.S.C. 154(b)(1)(B), 37 CFR 1.702(b) provides, in pertinent part, that:

Failure to issue a patent within three years of the actual filing date of the application. Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application[.]

<sup>2</sup> As of the date the patent issued on June 23, 2009, the application was pending three years and 268 days.

<sup>3</sup> 37 CFR § 1.702, provides grounds for adjustment of patent term due to examination delay under the Patent Term Guarantee Act of 1999 (original applications, other than designs, filed on or after May 29, 2000).

(a) Failure to take certain actions within specified time frames. Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to:

(1) Mail at least one of a notification under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151 not later than fourteen months after the date on which the application was filed under 35 U.S.C. 111(a) or fulfilled the requirements of 35 U.S.C. 371 in an international application;

<sup>4</sup> A restriction requirement was not mailed until May 5, 2008, fourteen months and 284 days after the date the all 35 U.S.C. 371 requirements were completed on May 26, 2006.

88 U.S.P.Q. 2d 1538 (D.D.C. 2008). Patentees asserts that pursuant to Wyeth, a PTO delay under §154(b)(1)(A) overlaps with a delay under §154(b)(1)(B) only if the delays "occur on the same day." Patentees maintain that the total non-overlapping PTO delay under § 154(b)(1)(A) & (B) is 552 (284 + 268) days as these periods do not occur on the same day. Accordingly, patentees assert entitlement to a patent term adjustment of 416 days.

Patentees further assert that the period reduction of 72 days under 37 CFR 1.704(c)(10) for filing an amendment under § 1.312 and drawings on April 13, 2009, after the mailing of the notice of allowance, is incorrect. Rather, the period adjustment set forth in § 1.703 should be reduced by only 2 days.

#### OPINION

Patentees dispute the reduction of 72 days for filing the amendment under § 1.312 on April 13, 2009, after the mailing of the notice of allowance pursuant to 37 CFR 1.704(c)(10). Specifically, patentees assert that the Office mailed a "Response to Rule 312 Communication" in response to the amendment on April 15, 2009. Patentees contend that the period of reduction should be 2 days (not 72 days), counting the number of days beginning on the filing date of the amendment under § 1.312, April 13, 2009, and ending of the mailing date of the "Response to Rule 312 Communication", April 15, 2009, in response to the amendment under § 1.312.

It is noted that 37 CFR 1.704(c)(10) provides that:

Submission of an amendment under § 1.312 or other paper after a notice of allowance has been given or mailed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the lesser of:

(i) The number of days, if any, beginning on the date the amendment under § 1.312 or other paper was filed and ending on the mailing date of the Office action or notice in response to the amendment under § 1.312 or such other paper;

or

(ii) Four months;

In this instance, the record reveals that the Office took action in response to the filing of amendment under § 1.312 on April 15, 2009. Accordingly, the period of adjustment of the term of the patent should have been reduced by 3 days, beginning on the date the amendment under 37 CFR 1.312 was filed, April 13, 2009 and ending on the mailing date of the response to the amendment under 37 CFR 1.312 was mailed, April 15, 2009. Accordingly, the period of reduction of 72 days will be removed and a period of reduction of 3 days will be entered.<sup>5</sup>

With regard to the argument under 37 CFR 1.702(b), patentees' interpretation of the period of overlap has been considered, but found inconsistent with the Office's interpretation of the overlap provision, 35 U.S.C. 154(b)(2)(A).

Patentees' interpretation of the period of overlap has been considered, but found inconsistent with the Office's interpretation of the overlap provision, 35 U.S.C. 154(b)(2)(A). 35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

to the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

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<sup>5</sup> It is noted that patentees assert that only 2 days of reduction to the patent term adjustment should be entered for the filing of the amendment under 37 CFR 1.312, however, the period of reduction to the patent term adjustment under 37 CFR 1.704(c)(10) begins on, and includes, the date the amendment under 37 CFR 1.312 was filed and ends on, and includes, the mailing date of the response to the amendment under 37 CFR 1.312. "When a period is indicated (in 37 CFR 1.703 or 1.704) as 'beginning' on a particular day, that day is included in the period, in that such day is 'day one' of the period and not 'day zero.'" MPEP 2731. "For example, a period beginning on April 1 and ending on April 10 is ten (and not nine) days in length." *Id.* Thus, in this instance, the period of reduction to the patent term adjustment is 3 days.

As explained in *Explanation of 37 CFR 1.703(f)*<sup>6</sup> and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154(b)(1)(B). Accordingly, the Office implements the overlap provision as follows:

If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A). Thus, any days of delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. See 35 U.S.C. 154(b)(1)(B), 35 U.S.C. 154(b)(2)(A), and 37 CFR § 1.703(f). See *Changes to Implement Patent Term Adjustment Under Twenty Year Term; Final Rule*, 65 Fed. Reg. 56366 (Sept. 18, 2000). See also *Revision of Patent Term Extension and Patent Term Adjustment Provisions; Final Rule*, 69 Fed. Reg. 21704 (April 22, 2004), 1282 Off. Gaz. Pat. Office 100 (May 18, 2004). See also *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, 69 Fed. Reg. 34283 (June 21, 2004).

Further, as stated in the *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, the Office has consistently taken the position that if an application is entitled to an adjustment

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<sup>6</sup> Likewise, 37 CFR 1.703(f) provides that:

To the extent that periods of delay attributable to the grounds specified in §1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.

under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

This interpretation is consistent with the statute. Taken together the statute and rule provide that to the extent that periods of delay attributable to grounds specified in 35 U.S.C. 154(b)(1) and in corresponding §1.702 overlap, the period of adjustment granted shall not exceed the actual number of days the issuance of the patent was delayed.

In this instance, the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A) is the period during which the application was pending before the Office, May 26, 2006, the date of completion of all requirements under 35 USC 371(b), to June 23, 2009, the date of the issuance of the patent (not including any other periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)).

Pursuant to 35 U.S.C. 154(b)(1)(A) and 37 CFR 1.702(a)(1), 284 days of patent term adjustment were accorded during the pendency of the application for Office delay prior to the issuance of the patent. Pursuant to 35 U.S.C. 154(b)(1)(B) and 37 CFR 1.702(b), 268 days of patent term adjustment accrued for Office issuance of the patent more than three years after the date of commencement of the national stage pursuant to 35 USC 371(f). All of the 268 days of patent term adjustment under 37 CFR 1.702(b) overlap with the 284 days of patent term adjustment under 37 CFR 1.702(a)(1). Entry of both the 284 days and the 268 days is neither permitted nor warranted. 284 days is the actual number of days issuance of the patent was delayed.

#### CONCLUSION

In view thereof, the patent term adjustment indicated on the patent should be 147 days (284 days of Office delay - 137 (52 + 82 + 3) days of applicant delay).

This matter is being referred to the Certificates of Correction Branch for issuance of a certificate of correction in order to

rectify this error. The Office will issue a certificate of correction indicating that the term of the above-identified patent is extended or adjusted by **147 days**.

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e). No additional fees are required.

Telephone inquiries specific to this matter should be directed to Kenya A. McLaughlin, Petitions Attorney, at (571) 272-3222.

*C. T. Donnell*  
Christina Tartera Donnell  
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Office of Petitions

Enclosure: Copy of DRAFT Certificate of Correction

UNITED STATES PATENT AND TRADEMARK OFFICE

**CERTIFICATE OF CORRECTION**

PATENT : 7,550,496 B2

DATED : Jun. 23, 2009

INVENTOR(S) : Matteucci, et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the cover page,

[\*] Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 USC 154(b) by (78) days

Delete the phrase "by 78 days" and insert -- by 147 days--